

EXHIBIT H

1 IN THE UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

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5 IN RE: VALSARTAN, LOSARTAN, AND MDL No. 2875
6 IRBESARTAN PRODUCTS LIABILITY LITIGATION

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8 THIS DOCUMENT RELATES TO ALL CASES

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11 * CONFIDENTIAL INFORMATION *
12 * SUBJECT TO PROTECTIVE ORDER *

13 Thursday, September 30, 2021
14 Volume II of II

15 VIDEOTAPED ORAL DEPOSITION OF
16 HERMAN J. GIBB, Ph.D., M.P.H.,
17 conducted at the law offices of Greenberg Traurig,
18 LLP, 2101 L Street, NW, Washington, DC 20037,
19 commencing at 8:35 a.m. EDT, on the above-referenced
20 date.

21 Reported by: Linda S. Kinkade, RDR CRR RMR RPR CSR

22

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<p>Page 350</p> <p>1 epidemiology studies and...</p> <p>2 Q. So the vast majority, if not all of the</p> <p>3 studies that you've been asked about in this case,</p> <p>4 relate to NDMA; is that correct?</p> <p>5 A. Right.</p> <p>6 Q. Did you review any NDEA papers or studies</p> <p>7 in performing your review of the case?</p> <p>8 A. There were studies that looked at NDEA. I</p> <p>9 mean, in particular, there was one by Zheng, et al.</p> <p>10 that -- it was a case-control study that reported</p> <p>11 there was an association between NDEA and I think it</p> <p>12 was -- I believe it was pancreatic cancer. But,</p> <p>13 curiously, there was no association with NDMA. But</p> <p>14 based on -- but I cannot conclude that there's an</p> <p>15 association with NDEA based on one study, and other</p> <p>16 studies yeah, so, I mean, there's only one study. It</p> <p>17 was a case-control study.</p> <p>18 Q. Can you base a causal association on the</p> <p>19 results of just one study?</p> <p>20 A. No. I mean, absolutely not. I mean, it</p> <p>21 was not -- it was -- the strength of association</p> <p>22 was -- it was not -- it was a weak strength of</p> <p>23 association. There's no consistency with other</p> <p>24 studies so -- and, as I indicated, odds ratios -- this</p> <p>25 is a limitation -- the odds ratios can exaggerate the</p> <p>Page 351</p> <p>1 relative risk, and I cite to Davies, et al. And</p> <p>2 following the Davies paper, an odds ratio of 2.28,</p> <p>3 which is weak anyway, would translate to a relative</p> <p>4 risk of less than 1.5.</p> <p>5 Q. Do you take into account the quality of the</p> <p>6 study when rendering your opinions?</p> <p>7 A. Oh, absolutely.</p> <p>8 Q. Is a case-control study, how does that</p> <p>9 compare to the cohort studies that you've cited in</p> <p>10 your paper?</p> <p>11 A. It's not as strong a design as the cohort</p> <p>12 study in evaluating risk.</p> <p>13 Q. Can you extrapolate from the NDMA studies</p> <p>14 to draw a causal association between NDEA and cancer?</p> <p>15 MR. NIGH: Form objection.</p> <p>16 A. Can I extrapolate from the NDMA for -- for</p> <p>17 NDEA?</p> <p>18 Q. Right.</p> <p>19 A. No, absolutely not. In fact, it was</p> <p>20 curious that Zheng found or claimed an association,</p> <p>21 found an odds ratio, NDEA, but not NDMA, which is sort</p> <p>22 of the opposite of what you might think, so...</p> <p>23 Q. What is your opinion with regard to whether</p> <p>24 the epidemiology supports a causal association between</p> <p>25 NDEA and cancer?</p>	<p>Page 352</p> <p>1 A. There's no evidence. I mean, there is no</p> <p>2 evidence of a causal association. There's just not.</p> <p>3 You can't have consistency when you only have one</p> <p>4 study, the strength of association is weak, the -- so</p> <p>5 it just -- it's not. There's just -- there's no</p> <p>6 evidence for NDEA.</p> <p>7 Q. Okay. And, again, when you were asked</p> <p>8 about the dietary studies, you were asked questions</p> <p>9 about -- you were asked questions about some cohort</p> <p>10 studies and some case-control studies.</p> <p>11 A. Right.</p> <p>12 Q. So what is the difference between a cohort</p> <p>13 and a case-control study?</p> <p>14 A. So a cohort study is where you're starting</p> <p>15 with a group that -- and where you identified what the</p> <p>16 exposure is and follow them forward in time. With a</p> <p>17 case-control study, you start with the cases and --</p> <p>18 who have a disease, and then you go -- and controls,</p> <p>19 and then you determine what their exposure is.</p> <p>20 Q. Which one is better at determining a causal</p> <p>21 association?</p> <p>22 A. Well, I would always want to rely on cohort</p> <p>23 studies to evaluate the risk. And I think the same is</p> <p>24 true in determining a causal association. If I have</p> <p>25 several cohort studies and some case-control studies,</p> <p>Page 353</p> <p>1 I'm going to look at the cohort studies first.</p> <p>2 Q. Mr. Nigh discussed with you the Loh study.</p> <p>3 Do you recall the ultimate finding of that study?</p> <p>4 A. Yes, I recall that.</p> <p>5 Q. Mr. Nigh referred to the finding of Loh as</p> <p>6 to rectal cancer showing a 46 percent increased risk.</p> <p>7 Do you recall that?</p> <p>8 A. I recall the -- that was for what endpoint</p> <p>9 was it? For colorectal cancer, you said?</p> <p>10 Q. Rectal cancer.</p> <p>11 A. Rectal cancer, right.</p> <p>12 Q. Let me ask you, is increased risk the same</p> <p>13 as causal association?</p> <p>14 A. No, it's not.</p> <p>15 Q. Can you explain that?</p> <p>16 A. You can look at results of individual</p> <p>17 studies, but, at the end of the day, you have to look</p> <p>18 at issues such as the strength of association, how</p> <p>19 strong is the association. 1.46 is not -- is a weak</p> <p>20 association. You have to look at consistency with</p> <p>21 other studies. You'd have to look at -- you'd want to</p> <p>22 look at dose response in the studies.</p> <p>23 So it's not a causal association. I mean,</p> <p>24 pulling out individual studies and saying, well, this</p> <p>25 showed this risk, perhaps, but in another study that's</p>
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